

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

in re the Application₊of:

Group Art Unit: 1614

Jun Feng et al.

Examiner: Not Yet Assigned

Serial No.: 10/809,636

Filed: March 24, 2004

For: DIPEPTIDYL PEPTIDASE

INHIBITORS

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449, and copies are included for the Examiner's convenience. As the Office no longer requires copies of U.S. patents and applications, the U.S. copies are not being submitted with this IDS. However, if the Examiner would like copies of the U.S. cited references, Applicants will provide the references upon request. The item listed on the attached form PTO-1449 at "EN" is a non-English language article. In accordance with 37 CFR § 1.98(a)(3)(i), the following is a concise explanation of the relevance of this article:

The article by P.O. Bezuglyi relates to the synthesis of arylsulfonyl hydrazides of 3-R-quinazolone-4-carbonyl-2-acid.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

INFORMATION DISCLOSURE STATEMENT FILING PROVISION:

\boxtimes	This I	OS is believed to be timely in that it is being submitted under 37 CFR §
•	•	is (1) within three months of the filing date of the application, which is not a
	•	osecution application filed under § 1.53(d); or (2) within three months of
-		ational stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a
		tion on the merits; or (4) before the mailing of a first Office action after filing
a requ	est for	continued examination under § 1.114. Thus, no fee is required.
		However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR §1.17(p) to the deposit account referenced below.
		However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.
	action	OS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice under 37 CFR § 1.311.
		The fee due under 37 CFR § 1.17(p) is submitted herewith.
		A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
payme	37 CFI ent of th	OS is being submitted under 37 CFR § 1.97(d), that is after a Final Action R § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before ne issue fee. A statement under 37 CFR § 1.97(e) is included below. The er 37 CFR § 1.17(p) is submitted herewith.
		STATEMENT UNDER 37 CFR § 1.97(e):
	Each i	tem contained in this IDS was first cited in any communication from a
foreigr	n paten	t office in a counterpart foreign application not more than three months
prior to	the fil	ing of this IDS.
	No ite	m contained in this IDS was cited in a communication from a foreign patent
office	in a co	unterpart foreign application, and, to the knowledge of the person signing

this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

	Payment and/or Authorization to Charge Fees:
	A check in the amount of is enclosed for the above fee(s).
□ .	Please charge to Deposit Account No. 50-2256 for the above fee(s).
	Although Applicants do not believe any fees are required, the Commissioner is
autho	rized to charge any fees required by the filing of these papers to Syrrx's Deposit
Accou	ınt No. 50-2256 .
-	Respectfully submitted,
	SYRRX, INC.
Dated	By: David J. Weltz
Dated	l: February 18, 2005 By:

Customer No. **32793**Syrrx, Inc.
10410 Science Center Drive
San Diego, CA 92121
Tel: (858) 622-8528

Fax: (858) 550-0992

Substitute for form 1449A/PTO					Complete if Known	
		Application Number	10/809,636			
INFO	RMATION	DIS	CLOSURE	Filing Date	March 24, 2004	
STAT	STATEMENT BY APPLICANT		First Named Inventor	Jun Feng		
				Group Art Unit	1614	
	(use as many she	ets as	necessary)	Examiner Name	Not Yet Assigned	7
Sheet	1	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C1	

			U.S. PATENT [OCUMENTS	P
Examiner	Cite	Document Number	Publication Date/	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant
Initials *	No.1	Number - Kind Code ² (if known)	Issue Date MM-DD-YYYY		Passages or Relevant Figures Appear
	AA	US1974/3823135	07-09-1974	Pilgram et al.	
	AB	US1996/5512549	04-30-1996	Chen et al.	
	AC	US1996/5580979	12-03-1996	Bachovchin	
	AD	US1997/5614492	03-25-1997	Habener	
	AE	US2000/6156739	12-5-2000	Griffin et al.	
	AF	US2000/6166063	12-26-2000	Villhauer	
	AG	US2001/6258597-B1	07-10-2001	Bachovchin	
	AH	US2001/0020006-A1	09-06-2001	Demuth et al.	
	Al	US2001/6303661-B1	10-16-2001	Demuth et al.	
	AJ	US2001/6319893-B1	11-20-2001	Demuth et al.	
	AK	US2001/0051646-A1	12-13-2001	Demuth et al.	
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	AO	US2002/0082427-A1	06-27-2002	Demuth et al.	
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	AQ	US2002/0198242-A1	12-26-2002	Demuth et al.	
	AR	US2002/0198380-A1	12-26-2002	Belzer et al.	
	AS	US2002/6500804-B2	12-31-2002	Demuth et al.	
	AT	US2003/0008925-A1	01-09-2003	Demuth et al.	
	AU	US2003/6548481-B1	04-15-2003	Demuth et al.	
	AV	US2003/0092630-A2	05-15-2003	Demuth et al.	
	AW	US2003/0119750-A1	06-26-2003	Demuth et al.	
	AX	US2003/0130199-A1	07-10-2003	von Hoersten et al.	
	AY	US2003/0134802-A1	07-17-2003	Demuth et al.	
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_	BA	US2003/0148961-A1	08-07-2003	Heiser et al.	
	BB	US2003/0153509-A1	08-14-2003	Bachovchin et al.	
	BC	US2003/0162820-A1	08-28-2003	Demuth et al.	
	BD	US2003/0166578-A1	09-04-2003	Arch et al.	
	BE	US2003/6620910-B1	09-16-2003	Calas et al.	
	BF	US2003/0176357-A1	09-18-2003	Pospisilik et al.	_
	BG	US2003/0199451-A1	10-23-2003	Mogensen et al.	
	вн	US2003/0199672-A1	10-23-2003	Knudsen et al.	

Examiner	Date
Signature	Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Su	Substitute for form 1449A/PTO				Complete if Known		
			_		Application Number	10/809,636	
11	NFO	RMATION	DIS	CLOSURE	Filing Date	March 24, 2004	
S	TAT	EMENT B	Y A	PPLICANT	First Named Inventor	Jun Feng	
					Group Art Unit	1614	
		(use as many she	ets as	necessary)	Examiner Name	Not Yet Assigned	
Sh	neet	2	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C1	

ВІ	US2003/0236272-A1	12-25-2003	Richard David Carr	
BJ	US2004/6703238-B2	03-09-2004	Bachovchin	
ВК	US2004/0054171-A1	03-18-2004	Jensen et al.	
BL	US2004/0058876-A1	03-25-2004	Hoffmann et al.	
ВМ	US2004/0132732-A1	07-08-2004	Han et al.	
BN	US2004/0167191-A1	08-26-2004	Demuth et al.	
ВО	US2004/0171555-A1	09-02-2004	Demuth et al.	

		FOREIGN PA	TENT DOCU	MENTS		
Evenine	Cina	Foreign Patent Document			Pages, Columns, Lines, Where	
Examiner Cit Initials* No	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	T ⁶
	BP	FR 2.162.106 (English Abstract-1973)	11-30-1972	Amschler et al.		
	BQ	. WO 89/10701	11-16-1989	BASF ·		
	BR	EP 0378255-A2	07-18-1990	Janssen Pharmaceutica		
	BS	GB 2230527-A	10-24-1990	Imperial Chemical Industries Plc		
	BT	WO 91/12001	08-22-1991	Merck & Co., Inc.		
	BU	WO 93/21162	01-28-1993	Nissan Chemical Industries, Ltd.		
	BV	WO 93/08259 (A2)	04-29-1993	New England Medical Center Hospitals, Inc.		
	BW	WO 93/08259 (A3)	04-29-1993	New England Medical Center Hospitals, Inc.		
	вх	EP 0547442-A1	06-23-1993	E.R. Squibb & Sons, Inc.		
	BY	WO 94/03055	02-17-1994	U.S. Government, Secty. HHS		
	BZ	EP 0587377-A2	03-16-1994	Eli Lilly and Company		
	CA	WO 95/35031	12-28-1995	La Trobe University		
	СВ	WO 96/32384	10-17-1996	Taiho Pharmaceutical Co., Ltd.		
	CC	WO 96/38550	12-05-1996	Dana-Farber Cancer Institute, Inc.		
	CD	. WO 97/40832	11-06-1997	Hans-Knoll-Institut Fur Naturstoff		
	CE	JP 9295977	11-18-1997	Terumo Corp.		
	CF	WO 98/00439	01-08-1998	Trustees of Tufts College		
	CG	WO 98/24780	06-11-1998	Amgen Inc.		
	СН	WO 99/16864	04-08-1999	Point Therapeutics, Inc.		
	CI	WO 99/38501	08-05-1999	Trustees of Tufts University	•	

Examiner	Dat	re
Signature	Coi	nsidered

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Substitute for form 14	49A/PTO		Complete if Known		
			Application Number	10/809,636	
INFORMAT	TION DIS	CLOSURE	Filing Date	March 24, 2004	
STATEMENT BY APPLICANT		First Named Inventor	Jun Feng		
			Group Art Unit	1614	
(use as m	any sheets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet 3	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C1	

CJ	WO 99/50249	10-07-1999	Du Pont Pharmaceuticals	
СК	WO 99-61431	12-02-1999	Company Probiodrug	
CL	WO 99/67278	12-29-1999	Pro-Biodrug	
CM	WO 99/67279	12-29-1999	Pro-Biodrug	
CN	WO 00/07617	02-17-2000	Novo Nordisk	<u> </u>
CO	WO 00/09666			
CP		02-24-2000	U.S. Government, Secty. HHS	ļ
	WO 00/15211	03-23-2000	Akesis Pharmaceuticals, Inc.	
CQ	WO 00/76986-A1	04-11-2000	Probiodrug	
CR	WO 00/34241	06-15-2000	Novartis AG	
CS	WO 00/47219	08-17-2000	Ontogeny, Inc.	ļ
СТ	WO 00/53171	09-14-00	Molteni L. E C. Dei Fratelli Alitti Societa' Di Esercizio S.P.A.	
CU	WO 00/57721	10-05-2000	Akesis Pharmaceuticals, Inc.	
CV	WO 01/14318-A2	03-01-2001	Probiodrug	
CW	WO 01/34594-A1	05-17-2001	Guilford Pharmaceuticals, Inc.	
CX	WO 01/52825-A2	07-26-2001	Novartis AG	
CY	WO 01/56988-A1	08-09-2001	Kirin Beer Kabaushiki Kaisha	
CZ	WO 01/70729-A1	09-27-2001	Sanofi-Sythelabo	
DA	WO 01/97808-A1	12-27-2001	Smithkline Beecham PLC	
DB	WO 02/34242-A2	05-02-2002	Probiodrug AG	
DC	WO 02/34243-A2	05-02-2002	Probiodrug AG	
DD	WO 02/083109-A1	10-24-2002	Ferring BV	
DE	JP 2002/338466	11-27-2002	Tanabe Seiyaku Co Ltd	
DF	WO 03/002593-A2	01-09-2003	Probiodrug AG	
DG	WO 03/002595-A2	01-09-2003	Probiodrug AG	
DH	WO 03/002596-A2	01-09-2003	Probiodrug AG	
DI	WO 03/016335-A2	02-27-2003	Probiodrug AG	
DJ	WO 03/022871-A2	03-20-2003	Probiodrug AG	
DK	WO 03/026652-A1	04-03-2003	Bristol-Myers Squibb Company	
DL	WO 03/030946-A1	04-17-2003	Novartis AG	
DM	WO 03/033524-A2	04-24-2003	Probiodrug AG	
DN	JP 2003/128551	05-08-2003	Sankyo Co LTD	
DO	WO 03/040174-A2	05-15-2003	Probiodrug AG	
DP	WO 03/045228-A2	06-05-2003	Trustees of Tufts College	
DQ	WO 03/045977-A2	06-05-2003	Trustees of Tufts College	
DR	WO 03/048081-A2	06-12-2003	Bristol-Myers Squibb Company	
DS	WO 03/048158-A1	06-12-2003	Bristol-Myers Squibb Company	
DT	WO 03/057200-A2	07-17-2003	Novo Nordisk	

Examiner	Date	
Signature	Considered	

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Chiron Corporation

Smithkline Beecham Corporation

Probiodrug AG

Sankyo Co. Ltd.

Probiodrug AG

Takeda Chem Ind Ltd

Bristol-Myers Squibb Company

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			Complete if Known					
INFORMATION DISCLOSURE				Application Number Filing Date First Named Inventor		10/809,636 March 24, 2004 Jun Feng		
STATEMENT BY APPLICANT								
				Group Art Unit		1614		
	(use as many sheets as necessary)			Examiner Name		Not Yet Assigned		
Sheet	4	of	10	Attorney Docket No	umber	SYR-DPP-IV-5004-C1		
	DU I		/O 03/063903-A2	08-07-2003		Probiodrug AG		
	DV	V	/O 03/072556-A1	09-04-2003		Probiodrug AG		
	DW	W	O 03/082898-A2	10-09-2003		Probiodrug AG		
	DX	N	O 03/092605-A2	11-13-2003 Trustee		ees of Tufts College		
	DY	W	O 03/099279-A1	12-04-2003		Novartis AG		

12-04-2003

12-24-2003

03-04-2004

04-02-2004

04-15-2004

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JP 2004/123738-A

WO 2004/037176-A2

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS							
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²					
	EG	ARGAUD, DORIANE et al., Metaformin decreases gluconeogenesis by enhancing the pyruvate kinase flux in isolated rat hepatocytes, European J. Biochem. 213, 1341-1348 (1993).						
	EH	ASHCROFT, STEPHEN J.H. et al., Structure-activity relationships of alloxan-like compounds derived from uric acid, Br. J. Pharmac. (1986), 89 pp. 469-472.						
	EI	BAL, GUNTHER, Dipeptidyl Peptidase IV and Prolyl Oligopeptidase: Design, Synthesis and Evaluation of Substrates and Inhibitors, (2002) Universiteit Antwerpen.						
	EJ	BARAKAT, S.E.S., Synthesis and hypoglycemic activity of some new 3-[4- [[[(cyclohexylamino) carbonyl] amino]sulfony]phenyl]-4(3H)-quinazolinones, Az. J. Pharm. Sci., Vol. 25, (2000), pp. 48-57.						
	EK	BARAKAT, S.E.S., Synthesis and Hypoglycemic Activity of Some New 4(3H) -Quinazolinone Analogues, Saudi Pharmaceutical Journal, Vol. 8, No.4 (2000) pp.198-204.						
	EL	BAKER, B.R. et al., Irreversible Enzyme Inhibitors. On the Mode of Pyrimidine Binding of 5-alkyl and 5-Arylpyrimidines to Dihydrofolic Reductase (1,2), Journal of Heterocyclic Chemistry Vol. 4 (1967) pp. 39-48.						
	ЕМ	BELGODERE, ELENA et al., Synthesis of Substituted Pyrimidines, Study of the Structure and of the Tautomeric Equilibria, (1976) Chem. Abstracts, Columbus, OH Vol. 85 No. 9.						
	EN	BEZUGLYI, P.O. et al., Synthesis of anylsulfonyl hydrazide of 3-R-quinazolone-4-carbonyl-2-acid, Pharmaceutical Journal (1979), pp. 70-71.						

Examiner	Date
Signature	Considered

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INFO	RMATION	DIS	CLOSURE	Filing Date	March 24, 2004	
STAT	TEMENT B	Y A	PPLICANT	First Named Inventor	Jun Feng	
				Group Art Unit	1614	
	(use as many she	ets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet	5	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C1	

EO	BHADURI, A.P. et al., Urinary Metabolite of 2-Piperazino-3 (H)-4-Quinazolone (Centpiperalone), A Potent Blood Sugar Lowering Agent, Indian J. Biochem. Biophys., Vol. 12 (1975), pp. 413-414.
EP	BOURAS, MOHAMMED, et al., Metabolism of enterostatin in rat intestine, brain, membranes and serum: differential involvement of proline-specific peptidases, Peptides, Vol. 16, No. 3, (1995), pp. 399-405.
EQ	BRUN, JEAN-FREDERIC, et al., Effects of Oral Zinc Gluconate on Glucose Effectiveness and Insulin Sensitivity in Humans, Biological Trace Element Research Vol. 47 (1995), pp. 385-391.
ER	BUCKLEY, DI, Analysis of the Degradation of Insulinotropin [GLP-1 (7-37)] In Human Plasma and Production of Degradation Resistant Analogs.
ES	CHATTERJEE, A.K. et al., Effect of Centpiperalone in Insulin Deficient Diabetes, Indian Journal of Experimental Biology Vol. 18 (1980), pp. 1005-1008.
ET	CHATTERJEE, A.K. et al., Effect of Centpiperalone, a New Hypoglycemic Agent on Insulin Biosynthesis & Release from Isolated Pancreatic Islets of Rat, Indian Journal of Experimental Biology Vol. 20 (1981) pp.270-272.
EU	COPPOLA, GARY M. et al., 1-Aminomethylisoquinoline-4-carboxylates as Novel Dipeptidylpeptidase IV Inhibitors, Bioorganic & Medicinal Chemistry Letters Vol. 10 (2000), pp. 1555-1558.
EV	DEACON, CAROLYN F. et al., Degradation of Glucagon-Like Peptide 1 in Vitro Yields an N-Terminally Truncated Peptide That is a Major Endogenous Metabolite in Vivo, Journal of Clinical Endocrinology and Metabolism Vol. 80, No. 3 (1995), pp. 952-957.
EW	DEACON, CAROLYN F. et al., Both Subcutaneously and Intravenously Administered Glucagon-Like Peptide I Are Rapidly Degraded From the NH ₂ -Terminus in Type II Diabetic Patients and in Healthy Subjects, Diabetes, Vol. 44 (1996), pp. 1125-1131.
EX	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition Influences GLP-1 Metabolism in Vivo, Regulatory Peptides Vol. 64 Issues 1-3 (1996) p.30.
EY	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition Potentiates the Insulinotropic Effect of Glucagon- Like Peptide 1 in the Anesthetized Pig, Diabetes, Vol. 47 (1998), pp. 764-769.
EZ	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition as an Approach to the Treatment and Prevention of Type 2 Diabetes: a Historical Perspective, Biochemical and Biophysical Research Communications 294 (2002), pp. 1-4.
FA	DEMUTH, HANS-ULRICH et al., Rebuttal to Deacon and Holst: "Metaformin effects on depeptidyl peptidase IV degradation of glucagons-like peptide-1" versus "dipeptidyl peptidase inhibition as an approach to the treatment and prevention of type 2 diabetes: a historical perspective" Biochemical and Biophysical Research Communications 296 (2002) pp. 229-232.
FB	ENGEL, MICHAEL et al., The crystal structure of dipeptidyl peptidase IV (CD26) reveals its functional regulation and enzymatic mechanism, Proc. Nat. Acad. Sci. Early Edition (2003), pp. 1-6.
FC	FANTUS, I. GEORGE, et al., Mechanism of Action of Metformin: Insulin Receptor and Postreceptor Effects in Vitro and in Vivo, J. Clinical Endocrinology & Metabolism (1986), pp. 898-905.

Examiner	Date	
Signature	Considered	

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STA	TEMENT B	Y A	PPLICANT	First Named Inventor	Jun Feng	
			,	Group Art Unit	1614	
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Group Art Unit

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